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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,556	08/25/2000	Bernward Scholken	02481.1702	3278

22852 7590 07/29/2002

FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/29/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

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AUG 01 2002

FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, L.L.P.

Docketed 8/1/02 Attorney BCD/SJS
Case 24811702
Due Date 10/29/02
Action Final Resp / 11-Appel
By [Signature]

18-1-02

[Signature]
AUG 02 2002

Office Action Summary

Applicati n N .

09/645,556

Applicant(s)

SCHOLKENS ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Revision (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicant's response to the first office action of June 20, 2001, submitted December 20, 2001 (Paper No. 10) is acknowledged.

Applicant's remarks and amendment is persuasive to remove the rejections under 35 USC 102 and 112 in the previous office action.

Claims 4-18 are herein examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Maclaughlan et al. (WO 96/24373).

Maclaughlan et al. (WO 96/24373) discloses pharmaceutical compositions comprising ACE inhibitors generally and alacepril, benazepril, captopril, cilazapril, delapril, enalapril, enalaprilat, fosinopril, fosinoprilat, imidapril, lisinopril, prindopril, quinapril, ramipril, temocapril, trandolapril, ceranapril, moexipril, quinaprilat, spriapril, see particularly claims 1-5. The ACE inhibitor may be present in an amount from 1 to 200 mg, see page 31, lines 27-35 in particular.

Claims 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by FDA Orange Book Active Ingredient Detail Record Search.

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FDA Orange Book Active Ingredient Detail Record Search discloses a pharmaceutical composition comprising candesartan cilexetil as the active ingredient.

Note that the recitation of intended use does not further limit a claim drawn to a composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7 and 10-13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maclaughlan et al. (WO 96/24373).

Maclaughlan et al. (WO 96/24373) discloses the employment of ACE inhibitors generally and alacepril, benazepril, captopril, cilazapril, delapril, enalapril, enalaprilat, fosinopril, fosinoprilat, imidapril, lisinopril, prindopril, quinapril, ramipril, temocapril, trandolapril, ceranapril, moexipril, quinaprilat, spriapril specifically in a co-therapy in patients susceptible to congestive heart failure, see particularly claims 1-5, 9 and 11, see also page 7, lines 1-25. The ACE inhibitor may be present in an amount from 1 to 200 mg, see page 31, lines 27-35 in particular.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an ACE inhibitor in a method of preventing congestive heart failure in a patient.

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One of ordinary skill in the art would have been motivated to employ an ACE inhibitor in a method of preventing congestive heart failure in a patient because ACE inhibitors are known to be employed of methods of preventing circulatory disorders such as congestive heart failure in patients, see for example lines 1-25, page 7 of Maclaughlan et al.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (USPN 5,196,444).

Naka et al. (USPN 5,196,444) teaches the employment of a pharmaceutical composition comprising candesartan cilexetil, an angiotensin II antagonist as the active ingredient in the treatment of heart diseases and hypertension, see abstract and claims 1-9 in particular.

Naka et al. does not particularly teach the employment of its composition in the prevention of CHF.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ candesartan cilexetil, an angiotensin II antagonist as the active ingredient in the treatment of CHF.

One of ordinary skill in the art would have been motivated to employ candesartan cilexetil, an angiotensin II antagonist as the active ingredient in the prevention of CHF because development of CHF typically arises from essential hypertension or from heart conditions following myocardial infarction. Therefore an active agent that is known to treat hypertension and heart diseases generally, would be reasonably expected to prevent CHF.

Response to Arguments

Applicant's arguments filed 12/20/01 concerning Maclaughlan have been fully considered but they are not persuasive. Applicant argues that the population of MacLaughlan does not have

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an essentially maintained heart function. Note that MacLaughlan generally teaches the employment of an ACE inhibitor for the treatment or prevention of circulatory disorders including CHF, see for example page 7, lines 5-25.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
July 22, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200

Notice of References Cited	Application/Control No. 09/645,556	Applicant(s)/Patent Under Reexamination SCHOLKENS ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,196,444	03-1993	Naka et al.	
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

[Handwritten Signature]
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TECH CENTER 1600/2900

OMB No 0651-0011

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	02481.1702-00	Serial No.	09/645,556
Applicant	Bernard Schölkens et al.		
Filing Date	August 25, 2000	Group:	1618 1617

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
MS	5,190,970	03/1993	Pan et al.			
	5,266,583	11/1993	Ohtawa			
MS	5,308,846	05/1994	Allen et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	DE 4308504	09/1994	Germany			
MS	0 241 201	10/1987	Europe			
	0 540 209	05/1993	Europe			
	0747 050	12/1996	Europe			
	2 308 064	06/1997	Great Britain			
	WO 97/49392	12/1997	PCT Int'l.			
	WO 98/30216	07/1998	PCT Int'l.			
	WO 99/44590	09/1999	PCT Int'l.			
	WO 00/02543	01/2000	PCT Int'l.			
	WO 00/71751	11/2000	PCT Int'l.			
MS	WO 01/15674	03/2001	PCT Int'l.			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

MS	Database WPI, Week 19944, Derwent Publications Ltd., London, GB, AN 199-520858, XP-002166044, Masuda Yoshinobu, Honda Yayo, Minato Hisao: "Inhibitor of cerebral vasospasm"
	Robert T. Eberhardt et al., Angiotensin II Receptor Blockade: An Innovative Approach to Cardiovascular Pharmacotherapy, J. Clin Pharmacol 1993, 33:1023-1038, XP-001019614
	Charles T. Suer, Jr et al., Stroke Prevention by Losartan in Stroke-prone Spontaneously Hypertensive Rats, Journal of Hypertension 1993, 11 (supple 3) 537-542, XP-00109687
MS	Mel Blumenthal, Treatment of Congestive Heart Failure, Experience With Fosinopril, American Journal of Hypertension, Ltd. 1997, vol. 10, No. 10, Part 2, pgs. 289-298, XP-001019673

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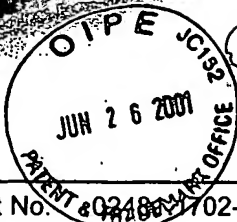
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INFORMATION DISCLOSURE CENTER

OMB No 0651-0011

Any. Docket No.	02481.1702-00	Serial No.	09/645,556
Applicant	Bernard Schölkens et al.		
Filing Date	August 25, 2000	Group.	1615 1617
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
mb	Fumiaki Nakamura et al., Chronic Administration of Angiotensin II Receptor Antagonist, TCV 16, In Cardiomyopathic Hamsters, American Physiological Society, 1994, pgs. 2297-2304, XP-001019610		
	K. Parfitt, Marundale - The Complete Drug Reference - Thirty-second Edition, 1999, Pharmaceutical Press, London, U.K., XP-002176301		
W	Derwent Abstract of DE 4308504		
Examiner	<i>[Signature]</i>		Date Considered 07/18/02
*Examiner	Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		
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JUN 28 2001
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Atty. Docket No. 024800-1702-00	Serial No. 09/645,556
Applicant Bernward Schölkens et al.	
Filing Date August 25, 2000	Group: 1615 1617

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appr priat
MS	5,952,305	09/1999	Pfeffer et al.			
I	5,972,990	10/1999	Pfeffer et al.			
MS	5,977,160	11/1999	Pfeffer et al.			

FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
MS	WO 93/20839	10/1993	PCT Int'l.			
I	WO 97/27745	08/1997	PCT Int'l.			
	WO 99/20260	04/1999	PCT Int'l.			
MS	199 13 428 A1	6/2000	Germany			Abstract

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
MS	Noriko Ogiku et al., Prophylactic Effect of Imidapril on Stroke in Stroke-Prone Spontaneously Hypertensive Rats; Stroke, (1993 Feb) 24 (2) 245-52, XP000997781
I	Charles T. Stier, Jr., et al., Enalapril Prevents Stroke and Kidney Dysfunction in Salt-Loaded Stroke-Prone Spontaneously Hypertensive Rats; Hypertension (Dallas), vol. 13, no. 2, 1989, pgs. 115-121, XP000997775
	Robert MKW Lee et al., Effects of perindopril on hypertension and stroke prevention in experimental animals, Can. J. Cardiol., vol. 10, no. Suppl. D, November 1994 (1994-11), pgs. 33D-36D; XP000998206
	J.E.F. Reynolds, "Martindale The Extra Pharmacopoeia, 1996, Royal Pharmaceutical Society, London XP002166043
	XP-002166044, Masuda Yoshinobu, Honda Yayoi, Minato Hisao: "Inhibitor of cerebral vasospasm," & JP 11 222439 A (17 Aug 99) abstract
MS	Derwent Abstract of DE 199 13 528 A1

Examiner <u>MS/K</u>	Date Considered 07/18/02
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	
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Atty. Dock # No.	02481.1702-00	Serial No.	09/645,556
Applicant	Bernard Schölkens et al.		
Filing Date	August 25, 2000	Group:	1615 1617

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Co-pending application no. 09/651,275, filed on August 30, 2000

Examiner	<i>[Signature]</i>	Date Considered	27/18/02
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